IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No.: 06-222 (JJF) **PUBLIC VERSION**

WYETH'S ANSWERING BRIEF IN OPPOSITION TO IMPAX'S MOTION TO COMPEL WYETH TO PRODUCE PROPERLY PREPARED RULE 30(b)(6) WITNESSES

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I. NATURE AND STAGE OF PROCEEDINGS

Impax first served Wyeth with a sweeping Rule 30(b)(6) notice on November 20, 2006, listing sixty-nine (69) broad topics. Impax amended its notice on January 22, 2007, but continued to list thirty-four (34) topics covering the same broad subject matter. [D.I. 82 at Ex. 1]. Failing to reach a compromise on the undue breadth of Impax's notice, Wyeth sought a protective order from this Court. [D.I. 81]. On March 2, 2007, the Court granted Wyeth's motion, acknowledging that Impax's notice had "correctly been attacked as overly broad" and suggesting that Impax re-notice the deposition "with a thought toward the amount of time on each substantive topic." [D.I. 106 at 14-15].

Impax then agreed to limit its examination to four days of testimony, but again did nothing to attempt to limit the breadth of its notice. [D.I. 113 at 4-5]. Instead Impax repackaged its notice into thirty-two (32) topics of the same or broader scope. [D.I. 113 at Ex. B]. Impax subsequently moved to compel a deposition pursuant to the Second Amended Notice (D.I. 112) and Wyeth opposed that motion. (D.I. 124). This Court ultimately granted Impax's motion, stating that a Rule 30(b)(6) deposition "is the most efficient way to proceed." [D.I. 146].

In light of the Court's ruling, Wyeth spent considerable time and effort preparing witnesses to respond to Impax's Second Amended Notice and four depositions have proceeded pursuant to portions of that Notice. Rather than confer with Wyeth on specific questions as Wyeth proposed, Impax filed this motion to compel, seeking an entire "do over" of two of the depositions it has taken based on its assertion that Wyeth's witnesses were not adequately prepared. This is Wyeth's answering brief in opposition to Impax's motion.

II. SUMMARY OF ARGUMENT

Impax's motion to compel should be denied out of hand because Impax flouted its obligations to meet and confer under D. Del. LR 7.1.1. Notwithstanding that its witnesses were adequately prepared, Wyeth offered to attempt to negotiate a resolution to avoid burdening the Court. Impax simply ignored Wyeth's express invitation and instead precipitously filed this motion. Wyeth, therefore, respectfully requests its attorney fees for the costs it has incurred in preparing this opposition as a result of Impax's failure to comply with D. Del. LR 7.1.1.

Impax's motion further should be denied because Wyeth's deponents were appropriately qualified and reasonably prepared to testify regarding the topics for which they were designated. Specifically, Impax's motion to compel relates to the first two depositions taken pursuant to Impax's Second Amended Notice–that of Dr. Robin Enever, which concerned six of the thirty-two Rule 30(b)(6) deposition topics, and of Dr. Richard Kavoussi, which concerned eight of those topics. Impax's four-day time limitation for its Second Amended Notice addressed *only* the *time* that Wyeth's designees would be physically available for questioning, and not the significant time that was required to prepare to testify on the wide-ranging topics. Dr. Enever :

preparing to testify on his six topics, and brought to the deposition an entire box of documents that directly relate to the topics for which he was designated. Dr. Kavoussi preparing to testify on his eight topics and brought to the deposition another three boxes of documents that directly relate to the topics for which he was designated. The preparation time identified for these witnesses does not include the significant additional time required to cull through the over one

million pages of documents produced to Impax to locate documents from which the information called for by Impax's Second Amended Notice could be gleaned.

Notwithstanding that Impax's Second Amended Notice seeks all manner of facts pertaining to events spanning a twelve-year period beginning seventeen years ago, Impax criticizes Wyeth's witnesses for not being able to respond to every conceivable question embraced by Impax's broadly worded deposition topics, and for actually having to review documents brought with them to the deposition to respond to some of the questions. Impax's position is untenable on numerous grounds.

First, it is entirely appropriate for a Rule 30(b)(6) witness to bring to a deposition documents from which answers to the deposition topics can be found. Rather than pursuing with the witnesses the documents that were brought to the deposition, however, Impax chose to simply ignore the documents and give the witnesses a memory test. That was neither reasonable nor appropriate.

Second, many of the questions Impax posed to the witnesses were beyond the scope of the topics for which they were designated. Needless to say, the witnesses were under no obligation to be prepared for such questions.

Third, given the scope of Impax's topics, it would be impossible to predict every conceivable question Impax could ask that would be within the scope of the topics. Rather than working with Wyeth to identify specific questions on which Impax truly sought answers, it proceeded with its broad topics. Yet, during the depositions, Impax ignored large portions of the noticed topics for which the designees were obligated to prepare. Thus, subsequent to the depositions complained of, Wyeth again asked Impax to

identify a narrower scope of questions to which it desired answers. Again, Impax ignored Wyeth's requests, instead seeking to burden the Court with this motion.

Lastly, Impax complains that Wyeth's witnesses did not have first hand knowledge, and failed to interview individuals with such knowledge. But Dr. Enever did have first hand knowledge regarding the subject matter of his topics, and Dr. Kavoussi is the individual at Wyeth who is currently responsible for clinical matters concerning to venlafaxine and EFFEXOR® XR, the general subject matter for which he was designated. The individuals who held that position at the time of the clinical trials in question are no longer with the company. Moreover, it is ironic that Impax now complains that Wyeth's designees did not interview individuals with first hand knowledge. In seeking to compel its Rule 30(b)(6) deposition, Impax argued that personal depositions of individuals with knowledge were not efficient because, based on the depositions in the earlier *Wyeth v. Teva* case, those individuals could not recall many of the facts that occurred many years ago. Yet now Impax complains that Wyeth's Rule 30(b)(6) designees did not interview those individuals, but instead prepared for the depositions primarily by collecting and reviewing contemporaneous documents.

In the end, Impax's refusal to focus the scope of its notice on the discovery it truly desired frustrated its own efforts at deposition to explore in minute detail, a very limited set of subjects encompassed only in part by the noticed topics, if at all. Impax has only itself to blame because it repeatedly has rebuffed Wyeth's numerous attempts to further define the topics on which Impax seeks discovery.

III. STATEMENT OF FACTS

A. Impax Failed To Meet And Confer

Impax complains that Wyeth witnesses Drs. Enever and Kavoussi were not adequately prepared to respond to the full range of noticed topics. But rather than address the specifics with Wyeth's counsel, Impax elected to burden the Court and Wyeth with a premature motion.

Drs. Enever and Kavoussi were deposed on May 18th and May 31st, respectively. Dr. Enever also was scheduled to testify on additional topics in Impax's Second Amended Notice on June 8th, but on the evening of June 5th, Impax abruptly declined to proceed with the deposition. [Ex. 1]. Wyeth promptly offered to reschedule the deposition (Ex. 2), despite learning that Impax was asserting that Wyeth had not adequately prepared Drs. Enever and Kavoussi. [*See* Exs. 3 and 23]. Although Wyeth disagreed with the assertion, it verbally offered several proposals to resolve the issue, and later confirmed these proposals in writing, stating, for example, that:

> Notwithstanding our disagreement as to the witnesses' level of preparation, in the spirit of cooperation, we are willing to discuss with you the possibility of providing additional information, either in the form of an interrogatory response or a limited amount of follow up deposition testimony. I suggested that you identify those portions of the deposition that Impax contends were not adequately addressed. I further suggested that the parties could then discuss whether such portions were fairly within the scope of the noticed topics and whether Wyeth agrees that these matters were not adequately addressed. I also suggested that, going forward, it would be helpful if Impax could limit the scope of the topics, since it has been increasingly apparent that Impax is not interested in every aspect of every topic it has noticed.

[Ex. 3 at 2]. In a brief voice mail communication, Impax's counsel refused to narrow the noticed topics, however, and *did not indicate whether Impax would identify those*

portions of the depositions that it contends were inadequate. [*See id.* at 2]. Still seeking to resolve the issue without court intervention and still unclear as to what Impax was seeking, Wyeth promptly proposed a teleconference to negotiate a suitable compromise. [*Id.*]. Impax did not respond to this offer, but instead filed this motion the following day, demanding, without limitation, a total "do over" for all topics on which Drs. Enever and Kavoussi had previously testified.

This is not the first time that Impax has failed to comply with the spirit and the letter of D. Del. LR 7.1.1. Indeed, this marks the *fourth time in four months* that Impax filed a motion without satisfying its obligation to meet and confer. [*See* D.I. 128 April 3, 2007 Withdrawal of Defendant's Motion for Protective Order to Govern Production of Documents in Response to Subpoena; D.I. 137 April 9, 2007 Withdrawal of Motion for Supplementation of the Protective Order; D.I. 188, May 22, 2007 Withdrawal of Motion to Compel Responses to Defendant's Request for Admission Nos. 1-3, 31, 38, 50, 62, 67, and 68]. In two of those instances, Impax did not withdraw its motion until the day, or day before, Wyeth's opposition was due, needlessly requiring Wyeth to prepare an opposition brief.

Here, Impax filed a Rule 7.1.1 certificate that counsel for Wyeth "has been contacted and the parties have been unable to resolve the issues presented in this Motion." [D.I. 207 at 2]. But this certificate is incorrect, because Impax has not even attempted to resolve these issues with Wyeth. Impax has not in good faith "made a reasonable effort to reach agreement with the opposing attorneys" as required by the local rule. Consequently, on this basis alone Impax's motion should be denied.

B. Dr. Enever's Qualifications And Preparation Concerning The Topics For Which He Was Designated To Testify

Wyeth designated Dr. Enever to testify as to Impax's noticed Topics 3, 4 (exclusive of human *in vivo* testing)[1], and 5 through 8.[2] [Ex. 4]. Topics 3 and 4 sought facts concerning Wyeth's development of EFFEXOR® XR for a period of time beginning seventeen years ago and spanning twelve years. In particular, Topics 3 and 4 include virtually all aspects of the development, composition (including methods, materials, and modifications), and *in vitro* release profiles of EFFEXOR® XR from June 1990 through

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[1] Impax's reference to the "*in vivo*" release profile of EFFEXOR® XR on page 4 of its opening brief appears to be in error.

[2] **Topic 3** recites "FACTS relating to the evolution of the composition and formulations of EFFEXOR XR and the development thereof from June 1990 through July 2002." [D.I. 113 at Ex. B].

Topic 4 recites "FACTS relating to the *in vitro* and *in vivo* release and bioavailability profiles of EFFEXOR XR from June 1990 through July 2002, including target profiles, when and where those profiles were first achieved, who was involved and oversaw this achievement, and what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles." [*Id.*].

Topic 5 recites "The composition of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in *hydrogel tablets*, and its development history from June 1990 through March 1996." [*Id.*].

Topic 6 recites "FACTS relating to the *in vitro* and/or *in vivo* release profiles of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in *hydrogel tablets*, from June 1990 through March 1996." [*Id.*].

Topic 7 recites "FACTS relating to the composition of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in *Gelucire capsules*, and the development thereof from June 1990 through March 1996." [*Id.*].

Topic 8 recites "FACTS relating to the *in vitro* and/or *in vivo* release profiles of an EXTENDED RELEASE FORMULATIONs by WYETH comprising VENLAFAXINE and *Gelucire capsules*, from June 1990 through March 1996." [*Id.*].

July 2002. [D.I. 113 at Ex. B at 1-2]. These two topics alone cover an enormous amount of ground, involving the efforts of a multitude of Wyeth personnel working on a host of disciplines over a twelve year period. Evidencing the intended breadth of these topics, Impax's Second Amended Notice excludes only the esoteric sub-categories "toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging" from the scope of some of these topics.

Dr. Enever joined Wyeth in March 1983 as the Director of Pharmacy Research and Development. [Ex. 5 at 7-8]. Over time, Dr. Enever's position advanced from Associate Director of Pharmaceutical Sciences, to Assistant Vice President of Pharmaceutics and Process Research and Development, to Senior Director of Pharmaceutics and Process Research and Development, to Assistant Vice President of Pharmaceutics and Process Research and Development and, currently, to Vice President of Pharmaceutical Sciences. [Ex. 5 at 7-8, 15-17]. During the course of his career, Dr. Enever

Thus, Dr. Enever was eminently suited to testify regarding historical facts of Wyeth's development program for extended release venlafaxine, to the extent such facts are reasonably available today.

As Impax is well aware, Dr. Enever did not simply rely upon his personal knowledge of the noticed topics,

including a review of the box of documents that he brought with him to the deposition. [Ex. 5 at 32:4-33:19; D.I. 209 at 10]. Impax chose not to ask Dr. Enever a single question regarding those documents, even though they contained information responsive to the noticed topics. Moreover, Impax ignored much of the subject matter embraced by Dr. Enever's noticed topics. As but one example, Impax chose not to ask a single question about post-1997 modifications to the method of manufacturing EFFEXOR® XR, despite Dr. Enever's careful preparation for that aspect of Topic 3. Instead, Impax spent much of the deposition asking questions that fell well outside the scope of the noticed topics.

C. Dr. Kavoussi's Qualifications And Preparation Concerning The Topics For Which He Was Designated To Testify

Wyeth designated Dr. Kavoussi to testify as to the *in vivo* and clinical aspects of Impax's noticed topics, in particular, in response to Topics 4 (human *in vivo* testing only), 10 (human *in vivo* testing only), 16, 17, 19 (Tables 2 and 3 only), 20, 25 (paragraph 20 of Wyeth's Reply only), and 26.[3] [Ex. 16]. These topics generally related

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[3] **Topic 4** recites "FACTS relating to the *in vitro* and *in vivo* release and bioavailability profiles of EFFEXOR XR from June 1990 through July 2002, including target profiles, when and where those profiles were first achieved, who was involved and oversaw this achievement, and what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles." [D.I. 113 at Ex. B].

Topic 10 recites "FACTS relating to the *in vitro* and/or *in vivo* release profiles of an EXTENDED RELEASE FORMULATION by WYETH comprising VENLAFAXINE and utilizing ALZA's OROS® oral delivery technology from June 1990 through July 2002, including target profiles, when those profiles were first achieved, where they were they [sic] achieved, who was involved and oversaw this achievement, what materials and

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methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles." [*Id.*].

Topic 16 recites "FACTS evidencing WYETH's knowledge and research prior to July 2002 demonstrating or refuting that the EXTENDED RELEASE FORMULATION comprising VENLAFAXINE claimed in the PATENTS IN SUIT provided a therapeutic blood plasma concentration of VENLAFAXINE over a twenty-four hour period with diminished incidences of nausea and emesis." [*Id.*].

Topic 17 recites "FACTS evidencing WYETH's knowledge and research prior to July 2002 demonstrating or refuting that the EXTENDED RELEASE FORMULATION comprising VENLAFAXINE claimed in the PATENTS IN SUIT eliminated the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of VENLAFAXINE." [*Id.*].

Topic 19 recites "FACTS supporting tables 1 though [sic] 3 of the PATENTS IN SUIT, including without limitation the data underlying Tables 1 through 3 and DOCUMENTS produced by WYETH evidencing that data." [*Id.*].

Topic 20 recites "The support for, the drafting of, the preparation of, and intended meaning of the following passage of the PATENTS IN SUIT:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount. [*Id.*].

Topic 25 recites "FACTS and DOCUMENTS CONCERNING the affirmative statements and denials in paragraphs 67 and 68 of WYETH'S REPLY." [*Id.*].

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to Wyeth's human research on extended release venlafaxine hydrochloride from June 1990 through July 2002, including the invention's improvement with respect to the adverse events of nausea and emesis (vomiting), portions of Wyeth's NDA for EFFEXOR® XR, and portions of the patents–in–suit relating to clinical data.

Dr. Kavoussi is presently Wyeth's Assistant Vice President in Neuroscience Clinical Research and Development,

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Topic 26 recites "FACTS evidencing the following parts and contents of NDA No. 20-699 including without limitation any amendments thereto through July 2002:

(a) Integrated Safety Summary

(b) Summary of Human and Pharmacokinetics and Bioavailability

(c)

(d)

[Id.].

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Dr. Kavoussi testified that in his previous role as Wyeth's Senior Director, Neuroscience Clinical Research and Development,

Prior to joining Wyeth, Dr. Kavoussi held the position of Senior Director in Neuroscience Clinical Research and Development at Pfizer where he

14:4-17]. During the course of his career, Dr. Kavoussi has become familiar with the analysis of clinical data and the practices of the FDA and foreign regulatory agencies regarding psychiatric medicines. [Ex. 17 at *e.g.*, 12:14-13:14; 23:22-24:21; 32:13-34:22]. Finally, Dr. Kavoussi has personal experience prescribing both immediate release venlafaxine and EFFEXOR® XR to patients,

Dr. Kavoussi

and arrived at the deposition with detailed notes (Ex. 18) and three boxes of documents that he had reviewed and liberally annotated with colored flags in the course of his preparation (Ex. 17 at 65:8-15; 186:3-24; 108:6-22; 203:3-204:7; 205:23-208:9). Impax ignored most of the documents Dr. Kavoussi brought with him to the deposition, and strayed far outside the scope of the noticed topics.

Wyeth further notes that Impax's motion concerns the preparation of only two of Wyeth's designees for thirteen of Impax's thirty-two noticed topics. Wyeth designee

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Angela Lukin in preparation for her testimony on six topics, including review of an additional four boxes of documents she brought to her deposition. Wyeth designee Lawrence Alaburda in preparation for his testimony on nine topics, including review of an additional two boxes of documents he brought to his deposition. Seven topics still remain for deposition. Again, the time identified for these witnesses is only a fraction of the time required to identify, organize, and assimilate the documents relevant to Impax's noticed topics.

IV. ARGUMENT

A. Impax's Motion Should Be Denied For Failure To Comply With Local Rule 7.1.1

D. Del. LR 7.1.1 states that unless otherwise ordered,

> the Court will not entertain any non-dispositive motion . . . unless counsel for the moving party files with the Court, at the time of filing the motion, a statement showing that the attorney making the motion has made a reasonable effort to reach agreement with the opposing attorneys on the matters set forth in the motion.

Here, Impax filed a statement certifying that:

> counsel for plaintiffs and counterclaim defendants Wyeth has been contacted and the parties have been unable to resolve the issues presented in this Motion.

[D.I. 207 at 2]. Rule 7.1.1 "was designed to facilitate resolution of disputes among the parties *before formally requesting the Court's aid by filing motions*." *DeWitt v. Penn-Del Directory Corp.*, 912 F. Supp. 707, 713 (D. Del. 1996), *rev'd. on other grounds*, 106 F.3d 514 (3d. Cir. 1997)(emphasis added). This Impax did not do.

Although Drs. Enever and Kavoussi in fact were adequately prepared and provided responsive testimony within the scope of the noticed topics, Wyeth nevertheless followed this Court's guidance by attempting to address with Impax the concerns it had

regarding the preparation of Wyeth's designees. In particular, Wyeth requested that Impax specifically identify the deposition testimony that Impax contends was inadequate and offered to provide additional information or testimony if appropriate. [*See* Ex. 3].

Responding by voice mail, Impax's counsel did not indicate whether it would identify those portions of the depositions that it contends were inadequate. [*Id.*] Impax further refused to acknowledge Wyeth's subsequent request for a telephonic meet and confer. Instead, it abruptly and unexpectedly filed its motion while Wyeth believed that negotiations were still in the early stages. Moreover, even in its present motion, Impax does not limit its request to particular topics or testimony, but merely demands, without limitation, a "do over" for all of the previously noticed topics on which Drs. Enever and Kavoussi already provided testimony.

The corresponding Federal Rule likewise "envisions a genuine two-way communication where the parties engage in a meaningful dialogue to resolve the issues without judicial intervention." *In re FedEx Ground Package Sys, Inc.*, 2007 WL 79312 *7 (N.D. Ind. Jan. 5, 2007)("Given the size and complexity of this litigation, [the party seeking discovery] should have made better attempts to resolve this discovery dispute before seeking judicial intervention pursuant to Fed.R.Civ.P. 37(a)."). It is therefore not appropriate for a party to merely communicate its general stance on an issue absent any type of meaningful discussions or negotiations. [*See id.*]. This Court has stated: "This type of effort cannot be construed as 'reasonable'." *DeWitt*, 912 F. Supp. at 713 (denying and striking motion to compel discovery responses where a party dissatisfied with a response to its discovery requests merely conveyed its general displeasure and intent to quickly move to compel without first attempting to reach agreement with the opposing

party); *see also Ansell Healthcare Prods. LLC v. Tillotson Corp.*, C.A. No. 06-527 (JJF) (D. Del. Apr. 13, 2007) (order denying motion to compel for, *inter alia*, failure to comply with D. Del. LR 7.1.1) [Ex. 22].

Here too, Impax's rush to seek the Court's assistance without adequate exploration of a compromise solution hardly qualifies as "a reasonable effort to reach agreement with the opposing attorneys" and is a violation of the meet and confer provision of the local rules. Impax's conduct is particularly egregious because it is the *fourth* time Impax has prematurely filed a motion with the Court without adequately conducting a meaningful dialogue with Wyeth in accordance with D. Del. LR 7.1.1. As such, Impax's motion was improperly filed and Impax should be ordered to pay Wyeth's attorneys' fees incurred in defending against this improper motion.

B. Wyeth's Witnesses Were Adequately Prepared To Testify As To The Noticed Topics

Rule 30(b)(6) was intended to "curb the 'bandying' by which officers or managing agents of a corporation are deposed in turn but each disclaims knowledge of facts *that are clearly known to persons in the organization* and thereby to it." Fed. R. Civ. P. 30(b)(6) Advisory Committee Notes, 1970 Amendment (emphasis added) (citation omitted). A Rule 30(b)(6) designee has an obligation to investigate information to respond to topics presented, but such information must be reasonably available to the corporation. Thus, a Rule 30(b)(6) designee is not required to conduct "detailed independent investigations beyond what is reasonably known to the company. That, in essence, would be to investigate [the deposing party's] case for him." *Banks v. Office of the Senate Sergeant-At-Arms*, 241 F.R.D. 370, 375 (D.D.C. 2007).

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Impax saddled Wyeth with the Herculean task of preparing its witnesses to respond to topics covering facts concerning extensive research and development efforts that began seventeen years ago and spanned twelve years, and that encompass virtually every aspect of Wyeth's program to develop and market an extended release formulation of venlafaxine hydrochloride. Wyeth provided two witnesses to address the noticed topics at issue here: Dr. Enever,

, and Dr. Kavoussi, a skilled clinician with expertise in the development of psychiatric drugs, having personal experience prescribing EFFEXOR® XR .

Lacking specific guidance as to the particular facts Impax sought, Drs. Enever and Kavoussi invested substantial time and energy investigating the full scope of the noticed topics by meeting with counsel and reviewing relevant documents. Impax argues that Drs. Enever and Kavoussi were unprepared because they had to rely on those documents. According to Impax: "To answer even simple questions, he [Dr. Kavoussi] had to comb through the three boxes of documents he brought with him." [D.I. 209 at 2]. But a Rule 30(b)(6) witness is entitled to rely on documents. Although "Rule 30(b)(6) puts several duties on the designating party and on the deponent, [] one of them is not omniscience." *Alexander v. Federal Bureau of Investigation*, 186 F.R.D. 137, 143 (D.D.C. 1998). *See also Equal Employment Opportunity Comm'n v. Am. Int'l. Group, Inc.*, 1994 WL 376052, at *3 (S.D.N.Y. July 18, 1994) ("Rule 30(b)(6) is not designed to be a memory

contest. It is not reasonable to expect any individual to remember every fact in an EEOC investigative file."). Notwithstanding that Dr. Enever brought an entire box of documents to the deposition that were responsive to the noticed topics, Impax failed to ask him a single question about those documents.

Impax apparently would have Drs. Enever and Kavoussi identify, locate, and interview the multitude of present and former Wyeth employees involved in planning, directing, and executing *twelve years* of pharmaceutical and clinical research occurring as long as seventeen years ago. But Dr. Enever's testimony, and Impax's own prior arguments to the Court in explaining its alleged need for a Rule 30(b)(6) deposition, demonstrate the difficulty in resurrecting personal memories of events occurring more than a decade ago—particularly when they involve highly specific details of a lengthy and involved R&D program.[4] The burden of such an undertaking here is clearly unreasonable, and made all the more so by the enormous breadth of the Second Amended Notice.

Specifically, Impax's prior brief underscores the difficulty in investigating the noticed topics through the personal memories of Wyeth's employees, arguing that "deposition transcripts for Wyeth's fact witnesses in the *Teva* litigation demonstrate that the persons who appeared to be participants in several key factual issues, such as (A) the development of EFFEXOR® XR … *were unable to recall … basic information on these*

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[4] Although certainly evidencing the difficulty of reconstructing the corporate decision making process from the early 1990's, Impax's citation to Dr. Enever's transcript on this point (*see* Ex. 5 at 150:6-14) is limited to the question of who at Wyeth would be most likely to know why one particular formulation was selected for further development over another. Dr. Enever did not testify that he could not identify any people with knowledge of any of the noticed topics.

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subjects, much less key details." [D.I. 113 at 15 (emphasis in original)].

Given the demonstrated difficulty in resurrecting detailed memories of some of the persons most intimately involved in Wyeth's program to develop an extended release formulation of venlafaxine hydrochloride from as far back as the early 1990's, Impax's expectation that Wyeth identify, contact, and interview what it acknowledged to the Court are potentially hundreds of people who were involved in various aspects of the program (D.I. 113 at 1) simply is unreasonable. And that burden is only compounded by the fact that

Although Impax points to *Bank of New York v. Meridien Biao Bank Tanzania Ltd.*, 171 F.R.D. 135, 151 (S.D.N.Y. 1997), to suggest that a Rule 30(b)(6) deponent has a duty to contact former employees, at least to the extent they are reasonably available, this view is not universal. In *Cupp v. Edward D. Jones & Co. L.P.*, 2007 WL 982336 (N.D. Okla. Mar. 29, 2007), for example, the Court ordered the Defendant to make a good faith effort to locate a witness known to have particularized information so that he might be *personally* deposed, but made clear that the corporation need not contact its former employee in preparation for its Rule 30(b)(6) deposition.

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C. Impax's Complaints Concerning Dr. Enever's Testimony Were The Result Of Either Questions Outside The Scope Of The Notice Or A Notice That Lacked Specificity

At pages 4-5 of its Brief, Impax identifies the questions that Dr. Enever was unable to answer. [D.I. 209]. But despite the sweeping breadth and lack of particularity of Impax's notice, many of those questions concern subject matter well outside of any reasonable interpretation of the topics for which he was designated. Any inability to testify precisely to matters "not designated in the deposition notice—cannot be deemed a violation of Rule 30(b)(6)." *LaForest v. Honeywell Int'l., Inc.*, 2004 WL 1811415, at *4 (W.D.N.Y. Aug. 11, 2004). More bluntly, "if the deponent does not know the answer to questions outside the scope of the matters described in the notice, then that is the examining party's problem." *King v. Pratt & Whitney*, 161 F.R.D. 475, 476 (S.D. Fla. 1995); *see also Banks*, 241 F.R.D. at 375 (finding deponent properly prepared to provide testimony under Rule 30(b)(6) based on the corporation's reasonable understanding of the noticed topics, notwithstanding a broader meaning urged by the noticing party).[5]

For example, Impax argues that Dr. Enever

("conception and reduction to practice of the alleged invention(s) claimed in each of the

[5] Even the cases Impax cites underscore that a Rule 30(b)(6) designee has "an affirmative obligation to be prepared *on the noticed topics*," and nothing more. *Donald M. Contracting, Inc. v. City of Newark*, 2006 WL 2724882, *5 (D. Del. Sept. 22, 2006) (emphasis added); *see also Novartis Pharms. Corp. v. Abbott Labs.*, 203 F.R.D. 159, 162 (D. Del. 2001) (Farnan J.) ("deponent has a 'duty of being knowledgeable *on the subject matter identified* as the area of inquiry.'") (emphasis added; citation omitted); *Mitsui & Co. (U.S.A.), Inc., v. P.R. Water Res. Auth.*, 93 F.R.D. 62, 67 (D.P.R. 1981) (corporation must prepare deponents to answer questions posed "as to the relevant subject matters").

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asserted claims of the PATENTS IN SUIT and claim 1 of U.S. Patent No 6,274,171 B1"), *a topic for which Dr. Enever was not designated.* Questions regarding

do not reasonably pertain to "the *composition and formulations* of EFFEXOR XR and the development thereof from June 1990 through July 2002," even if they are interpreted to include "when…they were developed" and "who developed them." [D.I. 113 at Ex. B at 1-2]. Moreover, the subject matter sought by these questions is also outside the scope of the Second Amended Notice because

are more properly related to Topic 1 (on conception). In fact, the deponent for that topic, Mr. Lawrence Alaburda testified that in preparation for his deposition,

Further, many of the questions that Impax contends were not adequately answered, *e.g.*,

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are not directed to the basic facts relating to "the evolution of the composition and formulations of EFFEXOR XR and the development thereof . . . includ[ing] modifications to the formulations during that period, methods of manufacturing, when and where they were developed, who developed them, and what materials and methods were used to develop them." Thus, Impax sought very specific information about the thought processes of specific Wyeth personnel that does not fall squarely within the scope of the Second Amended Notice. Specifically, Impax's Notice did *not* request testimony on "alternative manufacturing technology considered but not used," "the identity of decision-makers," or "*why* they were developed."

For the same reason, the thought process underlying

is also outside of the scope of the Second Amended Notice. Instead, the noticed topics were clearly directed to the physical development of EFFEXOR® XR and not the decision-making process surrounding the selection of one ingredient in the spheroid core.

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Impax's complaints that Dr. Enever could not answer highly detailed questions regarding the initial development of the *in vitro* release profile used in the development of Effexor® XR are also misplaced. [D.I. 209 at 4]. Contrary to Impax's allegations, Dr. Enever testified extensively on the *in vitro* release profile of EFFEXOR® XR, including the simulation and target profile used in the development of the product as indicated in Topic 4.

But there must be some bounds to a reasonable investigation and Impax's notice nowhere indicates that it was interested in these particular details.

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Moreover, details of Mr. Smith's calculations were explored at length in Mr. Smith's January 14, 2005 deposition taken during the *Wyeth v. Teva* litigation, which was produced to Impax months ago at WYETH 300-003907 through WYETH 300-004123.[6] *See Static Control Components, Inc. v. Lexmark Int'l., Inc.*, 2006 WL 3702464 (E.D. Ky. Dec. 13, 2006) (finding no merit to motion to compel continuation of Rule 30(b)(6) deposition where the information was otherwise obtained from fact witnesses).

Finally, even if some of the questions that Dr. Enever could not answer are deemed to be technically within the scope of Impax's Second Amended Notice, given the expansive scope encompassed by the noticed topics, Wyeth had no reason to know that testimony as to these specific matters was desired. Without specific guidance from Impax, Dr. Enever could not possibly have focused on each and every issue relating to the composition and *in vitro* release profiles of EFFEXOR® XR in the course of his

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preparation. The fact that a deponent may not be able to answer every single question asked during a Rule 30(b)(6) deposition does not mean that his testimony was deficient.[7]

D. Impax's Failure To Identify But One Or Two Questions Regarding Dr. Kavoussi's Testimony Highlights The Baselessness Of Its Motion

Notwithstanding its protestations that Dr. Kavoussi was not adequately prepared, Impax fails to identify in its brief any question within the scope of its Second Amended Notice that it contends Dr. Kavoussi was not prepared to answer other than the identification of the author(s) of a single specific document and the reason for that document's preparation. [D.I. 209 at 9]. Rather, Impax only asserts that Dr. Kavoussi "had no percipient knowledge regarding the topics for which he was designated" and did not "attempt[] to educate himself by talking with other Wyeth personnel." [*Id.* at 7].

Dr. Kavoussi testified, however, that

But, in view of his background in psychiatry, clinical psychiatry, and drug development (Ex. 17 at 192:1-19), Dr. Kavoussi stated that "given the topics I was being asked to cover, [ ] it was reasonable for me to review the documents, to review the data and -- in preparation for the deposition, and that I could answer the questions based on that." [Ex. 17 at 50:21-51:14]. In addition, Dr. Kavoussi supplemented his review of Wyeth's

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[7] By contrast, in *Marker v. Union Fidelity Life Ins. Co.*, on which Impax relies, Union Fidelity refused to provide a witness who could answer specific questions concerning the retrieval of computerized data despite the Court's finding that the "request was specific and understandable .... In fact, it was subject to a prior clarifying letter so that defendant necessarily knew the scope and nature of plaintiff's interest." 125 F.R.D. 121, 125-126 (M.D.N.C. 1989). Impax never provided any such clarification here, notwithstanding Wyeth's numerous requests that it do so.

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internal documents with numerous publications (Impax Dep. Ex. 101-107, 109), the deposition transcripts of two Wyeth Rule 30(b)(6) deponents in the *Teva* litigation (Impax Dep. Ex. 172-173), and complete sets of Dr. Hollander's and Dr. Thisted's expert reports from the *Teva* litigation (Impax Dep. Ex. 144, 89), making particular reference to Dr. Thisted's reports in his personal notes and testimony. [Ex. 17 at 65:16-68:4; 204:18-205:13; 209:18-210:3; Ex. 18].

Dr. Kavoussi's review of documents and reports was an entirely appropriate method to address Impax's noticed topics.

Contrary to Impax's assertion that "[w]henever Impax asked a question for which an answer did not appear on the face of a document, Dr. Kavoussi could not answer" (D.I. 209 at 9), in responding to Impax's questions, Dr. Kavoussi relied extensively on his knowledge gained through his work in the pharmaceutical industry. For example, in addressing Impax's questions as to why the document about which Impax now complains

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Dr. Kavoussi also testified to well over a decade of experience in clinical psychiatry. [Ex. 17 at 15:3-17:14]. During that time, Dr. Kavoussi treated patients with both the immediate release and extended release forms of venlafaxine hydrochloride, gaining personal experience with the therapeutic efficacy and adverse event profiles of venlafaxine which is pertinent to at least noticed Topics 16, 17, 20, 25, and 26.[8] Thus, for example, when asked whether he had any firsthand knowledge of any events relating to this litigation before he joined Wyeth, Dr. Kavoussi described his experience in prescribing the two commercial formulations of venlafaxine hydrochloride, immediate release EFFEXOR® and extended release EFFEXOR® XR. Describing his experience with the immediate release formulation, Dr. Kavoussi testified that

> ...the vast majority of patients were not able to tolerate it. There seemed to be very high rates of nausea with it, so I had very few patients that were able to stay on the drug ... so I prescribed it less and less as time went on.

[Ex. 17 at 18:11-19:14]. In contrast,

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[8] Topic 10 relates to *in vivo* release profiles of extended release formulations of venlafaxine hydrochloride utilizing Alza OROS® technology.

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> ...when the XR formulation came along, I was actually even reluctant to prescribe it again, but again, in some refractory patients or patients who didn't respond to other medicines, when I treated them, they seemed to be able to tolerate it. There were still nausea. It didn't go away completely, but it seemed to be very - - much better tolerated. At least they were able to stay on the medicine. The nausea seemed to go away fairly quickly and they were able to benefit from the medicine.

[Ex. 17 at 47:22-48:7]. "So in my clinical experience," testified Dr. Kavoussi, "there seemed to be a difference in terms of the rates of side effects, especially nausea and emesis that were occurring." [Ex. 17 at 19:25-20:3].

In sum, Wyeth's deponents were reasonably prepared to testify regarding the topics for which they were designated and the relief Impax seeks of an entire repeat of two full days of completed depositions is unwarranted.

V. CONCLUSION

For the foregoing reasons, Impax's motion to compel Wyeth to produce witnesses for additional testimony under Rule 30(b)(6) on noticed Topics 3 through 8, 10 (*in vivo* only), 16, 17, 19 (Table 2 and Table 3 only), 20, 25 (paragraph 20 of Wyeth's Reply only), and 26 should be denied. Furthermore, Wyeth should be awarded its attorneys' fees it incurred in preparing this opposition based on Impax's failure to comply with D. Del. LR 7.1.1 before filing its motion.

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CERTIFICATE OF SERVICE

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